Remarks

I. Status and Nature of the Amendment

Claims 1, 5-31 are believed to be presently pending in this application. All other claims have been withdrawn as directed to non-elected inventions. Due to Applicants' election of the species "cytokine," only claims 1, 5-9, 16, 17, and 26-31 have been examined.

Applicants greatly appreciate the Examiner's granting of a telephonic interview on July 7, 2003 regarding the status of the claims. Applicants noted that the Examiner's characterization of the claims of Group I in the Restriction Requirement of February 24, 2003, appeared incomplete since it failed to include the inventions of claims 10-25 in Group I. It is Applicants' understanding that claims 10-25 are included in the invention of Group I even though they may have been temporarily withdrawn from consideration due to Applicants' response to the requirement for an election of species, and that these claims will be examined in this application in the event that additional species are examined. Likewise, it is Applicants' understanding that claims 43-48 are included in the invention of non-elected Group IV, and would be examined in the event that Applicants file a divisional application directed to the invention of the Group IV claims. **Confirmation of Applicants' conclusions and clarification of the Examiner's actions are respectfully requested**.

II. The Rejection of Claims 1, 5-9, 16, 17, and 26-31 Under 25 U.S.C. § 112, Second Paragraph

Claims 1, 5-9, 16, 17, and 26-31 have been rejected under 25 U.S.C. § 112, second paragraph in light of their recitation of the term "sufficient." Specifically, the Examiner has questioned whether the term is defined by the claims and whether the specification provides a standard for ascertaining the requisite degree, such that one of ordinary skill would be reasonably apprised of the scope of the invention. Applicants respectfully traverse and request reconsideration.

At the outset, Applicants respectfully submit that the mere presence of the term "sufficient" in the claims does not render the claims indefinite (*Exxon Research And Engineering Company v. United States*, 54 USPQ2d 1519 (Ct. Fed. Claims 2000) http://www.ll.georgetown.edu/federal/judicial/fed/opinions/00opinions/00-5077.html).

Applicants further submit that the claims do provide definition of this term, and respectfully draw the Examiner's attention to the fact that the claims recite that the detected light signal be *sufficient* "for each of said target analytes to ensure that said reported presence, absence, activity or concentration of each target analyte is determined using data corresponding to a light signal that is within said known dynamic range of said assay for that target analyte." Thus, in the context of the present invention, a degree of signal is sufficient if it is of a magnitude that permits the presence, absence, activity or concentration of a target analyte to be determined within the dynamic range of the assay being employed. It is respectfully submitted that the inclusion of the term "sufficient" thus does not render the claims indefinite, and that the rejection may be properly withdrawn.

III. The Rejection of Claims 1, 5-9, 16, 17, and 26-31 Under 25 U.S.C. § 102(e) In Light of Herron *et al.* (U.S. 6,287,871)

Claims 1, 5-9, 16, 17, and 26-31 have been rejected under 25 U.S.C. § 102(e) in light of Herron *et al.* (U.S. Patent No. 6,287,871). Applicants respectfully traverse and request reconsideration.

As the Examiner will appreciate, any assay of an analyte will vary in its sensitivity as a function of analyte concentration. Thus, for example, if a solution contains excess amounts of an analyte, the assay may become "saturated" and cease to accurately report the analyte concentration. Likewise, if the solution contains insufficient amounts of the analyte, the assay may become unable to accurately report the analyte concentration. These considerations have led to the realization that an assay is a valid measure of an analyte's concentration only within a range of concentrations in which a change in assay report is proportional to the change in

the concentration of the analyte. Conventionally, this range is termed the "dynamic range" and is dependent upon both the analyte being assayed and the assay being used.

The Herron *et al.* patent teaches the use of a CCD camera to detect and assay analytes. It is respectfully submitted, however, that the invention defined by the present claims is quite distinct from the teachings of the Herron *et al.* patent. The present invention concerns a method for *enhancing* the dynamic ranges of multiple assays, so that each assay will be capable of accurately assaying its respective analyte throughout a broader range of analyte concentrations. The claimed invention involves the simultaneous and independent *enhancement* of the respective dynamic ranges of two or more analytes. As reflected in the claims, such enhancement is achieved by employing a computer system comprising a CCD camera detector that detects light signals generated by the respective assays. This data is compared with data corresponding to the light signal generated by a known concentration of each target analyte that is within the dynamic range of the assay being used for that analyte.

In the approach taken by Herron *et al.*, the CCD camera merely reports the signal elicited by the analytes being assayed. If the concentration of an analyte is below (or above) the dynamic range of the assay, the CCD report will provide an inaccurate report of the true concentration. The experimentalist would need to repeat the assay (or equivalently, conduct multiple assays in parallel) in which the assay time was increased, or the analyte diluted.

In contrast, in accordance with the present invention, a computer system compares the report of analyte concentration obtained by the CCD camera with the report that would be obtained by that analyte if its concentration were within the dynamic range of the assay. Thus, in the present invention, if the sample contains low levels of analyte, the assay time can be automatically increased. Likewise, if the sample contains excess levels of analyte, the assay time can be automatically decreased. The methods of the present invention permit such automatic adjustments to be made simultaneously with respect to each analyte being assayed. It is respectfully submitted that this advance is neither taught nor suggested in the cited Herron *et al.* patent.

Accordingly, Applicants respectfully submit that the present claims are not anticipated under 25 U.S.C. § 102 in light of Herron *et al.* (U.S. Patent No. 6,287,871). Applicants therefore respectfully submit that the rejection in light of Herron *et al.* (U.S. Patent No. 6,287,871) may be properly withdrawn.

IV. The Rejection of Claims 1, 5-9, 16, 17, and 26-31 Under 25 U.S.C. § 103(a) in light of

A. The Rejection of Claims 16 and 17 In Light of Herron *et al.* (U.S. 6,287,871) In View of Lehman *et al.* (U.S. 5,939,281)

The teachings of the Herron *et al.* Patent (U.S. 6,287,871) have been discussed above. The Lehman *et al.* Patent (U.S. 5,939,281) is stated to disclose the use of specific binding reagents, such as antibodies, for detecting the concentration of a cytokine. Applicants submit that the combined teachings of the cited references fail to render obvious the present invention which involves the use of a computer system to compare the signal elicited by an analyte of unknown concentration with the signal that would be elicited by that analyte within the dynamic range of the assay being used. Accordingly, Applicants respectfully submit that the cited Lehman *et al.* Patent fails to remedy the deficiency of the primary reference, and that the combined references thus fail to render Claims 16 and 17 obvious. Applicants therefore submit that the rejection of Claims 16 and 17 under 35 U.S.C. § 103(a) in light of Herron *et al.* (U.S. 6,287,871) and Lehman *et al.* (U.S. 5,939,281) may be properly withdrawn.

B. The Rejection of Claims 27 and 28 In Light of Herron *et al.* (U.S. 6,287,871) In View of Campbell *et al.* (U.S. 4,946,958)

The teachings of the Herron *et al.* Patent (U.S. 6,287,871) have been discussed above. The Campbell *et al.* Patent (U.S. 4,946,958) is stated to disclose the use of a chemiluminescent label in the analysis, assay or location of proteins. As in the case of the Lehman *et al.* Patent, Applicants submit that the combined teachings of the Herron *et al.* Patent and the Campbell *et al.* Patent fail to render obvious the present invention which involves the use of a computer system to compare the signal elicited by an analyte of unknown concentration with the signal that would be elicited by that analyte within the

dynamic range of the assay being used. Accordingly, Applicants respectfully submit that the cited Campbell *et al.* Patent fails to remedy the deficiency of the primary reference, and that the combined references thus fail to render Claims 27 and 28 obvious. Applicants therefore submit that the rejection of Claims 27 and 28 under 35 U.S.C. § 103(a) in light of Herron *et al.* (U.S. 6,287,871) and Campbell *et al.* Patent (U.S. 4,946,958) may be properly withdrawn.

C. The Rejection of Claim 30 In Light of Herron *et al.* (U.S. 6,287,871) In View of McMillan *et al.* (U.S. 6,057,163)

The teachings of the Herron *et al.* Patent (U.S. 6,287,871) have been discussed above. The McMillan *et al.* (U.S. 6,057,163) is stated to disclose the use of a microwell plate for detecting the amount of light emitted by a plurality of samples. As in the case of the Lehman *et al.* and Campbell *et al.* Patents, Applicants submit that the combined teachings of the Herron *et al.* Patent and the McMillan *et al.* Patent fail to render obvious the present invention which involves the use of a computer system to compare the signal elicited by an analyte of unknown concentration with the signal that would be elicited by that analyte within the dynamic range of the assay being used. Accordingly, Applicants respectfully submit that the cited McMillan *et al.* Patent fails to remedy the deficiency of the primary reference, and that the combined references thus fail to render Claim 30 obvious. Applicants therefore submit that the rejection of Claim 30 under 35 U.S.C. § 103(a) in light of Herron *et al.* (U.S. 6,287,871) and McMillan *et al.* (U.S. 6,057,163) may be properly withdrawn.

V. Concluding Remarks

Having now responded to all of the Examiner's rejections, Applicants respectfully submit that the present application is in condition for Allowance, and earnestly solicit early notice of such favorable action. The Examiner is respectfully invited to contact the undersigned with respect to any issues regarding this application.

Respectfully Submitted,

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